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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/509,196
Filing Date: March 23, 2000
Appellant(s): DALY ET AL.

Richard A. Schwartz
and
Carol L. Francis

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 28, 2006 appealing from the Office action mailed February 01, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Daly, Cell Signal, 1998, 10, 613-618 (cited by Appellant);

Daly et al, 1996, J. Biol. Chem., 271, 12502-10 (cited by Appellant);

Stein et al. (EMBO, 1994, 13, 6, 1331-40 (cited by Appellant);

Kishi et al. Biochem. Biophys. Res. Commun., 1997, 232, 5-9 (cited by Appellant);

Tanaka et al. Cancer Res., 1997, 57(1), 28-31 (cited by Appellant);

Baguley et al., 2004, European J. Cancer, Vol. 40, pp. 794-801

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 5-7, 19-22, 24-29 and 31-41 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. §

101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to isolated nucleic acid molecules and the proteins encoded thereby of as yet undetermined function or biological significance. The instant specification discloses sequences of a novel nucleic acid (SEQ ID NO: 1) and the encoded protein (SEQ ID NO: 2), designated 2.2412 and named "a candidate effector protein of the Grb7 family of signaling proteins" (page 1, lines 7-8, emphasis added). The specification describes that the interest in Grb7 family of proteins is that, "Grb7 family proteins exhibit differential expression in certain human cancers (particularly breast and prostate cancer) and may therefore be involved in tumour progression" (page 5, lines 13-15, emphasis added). The factual evidence characterizing this specific 2.2412 of SEQ ID NO: 2, encoded by the claimed polynucleotide of SEQ ID NO: 1 is limited to (1) the discovery that 2.2412 polypeptide is capable to bind to Grb14 protein within yeast two hybrid screen system (see pages 2 and 6-10 of the specification); and (2) description of the pattern of tissue distribution of 2.2412 protein, which is such that it is expressed "in all tissues examined with the exception of the kidney" (middle at page 10). Based on the information presented, the specification asserts the utility of instant claimed polynucleotides as being useful as cancer markers, "[d]etection of the protein encoded by the cDNA 2.2412 in a

sample should provide a useful tumor marker and prognostic indicator for [breast and prostate] cancers" (page 5, lines 13-19 of the instant specification).

The assertion that a novel 2.2412 protein encoded by the claimed polynucleotide is a candidate effector protein for the Grb7 proteins, which maybe associated with cancer, does not make the instant DNA or encoded protein diagnostic of cancer. The instant specification fails to provide any evidence or sound scientific reasoning to allow a conclusion that the instant 2.2412 protein encoded by the claimed polynucleotides is associated with any type of cancer, including prostate or breast cancer. A specification can meet the legal requirements of utility and enablement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide, or a well-established utility for the claimed polynucleotide would be *prima facie* obvious to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed polynucleotide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed polynucleotide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern here. The instant specification discloses that the claimed nucleic acid encodes a protein that binds Grb7 and Grb14 proteins *in vitro* and hypothesizes that the detection of claimed polynucleotides can be used for the diagnosis of cancer because Grb7 proteins are reported to be differentially expressed in certain primary cancers and cancer cell lines. However, there is no disclosure that the claimed polynucleotides are expressed at altered levels or forms in any specific, diseased tissue or

otherwise associated with any particular type of cancer, as implied by the instant specification. Therefore, one skilled in the art would have to engage in significant further research to discover how and if the 2.2412 protein is associated with what type of cancer the in order to use the claimed polynucleotides as cancer markers.

Furthermore, in the absence of knowledge of the biological significance of this specific nucleic acid and encoded protein or its relevance to cancer, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. The instant 2.2412 polypeptide was isolated based on its ability to bind within an artificial cellular model (yeast two hybrid screen system) to a protein (Grb14 protein), which belongs to a family of proteins potentially associated with certain types of cancer. Based on that discovery, it was further hypothesized that the 2.2412 encoding DNA could be useful as tumor marker (middle at page 5, for example). However, there is no evidence of record to show that 2.2412 polynucleotides are in fact differentially expressed in any tumors. On the contrary, it is clearly stated in the instant specification that "the new sequence is expressed in all tissues except kidney cells" (page 10, second paragraph). Based on this disclosure, one skilled in the art would reasonably conclude that the novel polypeptide 2.2412 cannot possibly be a specific marker for any cancer cells due to the its presence in "all tissues".

Thus, to employ the instant claimed 2.2412 DNA in the future methods of diagnosing cancer is not a "real world" because it would eventually relate to a protein for which no biological function or differential expression, which would support their asserted use as cancer marker, are known. To employ a nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined

by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the instant polynucleotides or the encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5-7, 19-22, 24-29 and 31-41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(10) Response to Argument

Beginning at page 7 of the Brief, Appellant traverses the rejection on the premise that the rejection is in conflict with the legal standards of 35 U.S.C. § 101. Specifically, Appellant submits that the "specification discloses at least two utilities for the claimed invention:

1) The claimed polynucleotides are useful in distinguishing cancer cells from normal cells because they are differentially expressed in certain human cancers, e.g., breast and prostate cancer; and

2) The claimed polynucleotides are useful for distinguishing cancer cells from normal cells because they encode a polypeptide (designated 2.2412) that binds to the signaling proteins Grb7 and Grb14, each of which are known to be differentially expressed in certain cancer cells relative to normal cells".

Appellant further argues at page 8 of the Brief that the Examiner dismisses evidence submitted in the cited publications and "appears to be confusing a statement of utility, which must be recited in the application as filed, with extrinsic evidence that supports such a statement". Appellant's arguments have been fully considered but are not persuasive for the reasons set forth below.

First, it is important to point out that the first asserted utility to use the claimed 2.2412 encoding polynucleotides as a marker for cancer appears to be lacking any factual evidence within the instant disclosure, as originally filed. Contrary to Appellant's statement, there is no information presented at the time of filing regarding 2.2412 being "differentially expressed in certain human cancers, e.g., breast and prostate cancer" (top at page 7 of the Response). The instant specification clearly states that 2.2412 is a ubiquitously expressed protein, which is present "in all tissues examined with the exception of the kidney" (middle at page 10 of the specification, as filed). Absent a disclosure of altered levels or forms of a polynucleotide encoding 2.2412 polypeptide in diseased tissue as compared with the corresponding healthy tissue, the claimed polynucleotide is not a biological marker.

With regard to diagnosis of disease, in order for a polynucleotide to be useful, as asserted, for diagnosis of a disease, there must be a well established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The presence of a

polynucleotide in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in specific disclosed levels in diseased tissue compared to normal tissue (i.e. overexpression). However, in the absence of any disclosed relationship between the claimed polynucleotides or the proteins that are encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotides or the encoded proteins with any known disease or disorder, any information regarding general tissue expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696. In the instant case, the disclosure does not present a specific and substantial utility that would support the requirement of 35 U.S.C. §101. The specification discloses the presence of 2.2412 polynucleotides in all tissues except kidney; however, Appellant argues that the claimed polynucleotides are differentially expressed and are, therefore, biological markers. Thus, it appears that Appellant's argument ignores and contradicts the evidence presented in the specification as originally filed.

With respect to the second asserted utility, Appellant argues that the claimed polynucleotides are useful as cancer markers because they encode proteins, which bind to Grb7 and Grb14 polypeptides, which are allegedly differentially expressed in cancerous cells relative to normal cells. However, the assertion that a novel 2.2412 protein encoded by the claimed polynucleotide is a candidate effector protein for the Grb7 proteins, wherein Grb proteins maybe associated with cancer, does not provide a scientific basis to conclude that the instant DNA or encoded protein can be used as tumor markers. There is no evidence of record that the instant 2.2412 exclusively binds to Grb7 or Grb14 proteins. The instant specification only teaches that 2.2412 is capable of binding to Grb14 within an experimental model (yeast two-hybrid system), which does not preclude 2.2412 protein to bind to other proteins. As such, it is not clear and is not explained in the instant specification, as filed as how 2.2412 could be used as a cancer marker based on its binding ability.

Further, in the context of determining whether sufficient utility has been alleged "it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct" *In re Jolles,* 628 F. 2d 1322 [206 USPQ 885] (Fed. Cir. 1980), *citing In re Novak,* 306 F. 2d 924 [134USPQ 335]. In the instant case, because the asserted utility of the 2.2412 protein as a cancer marker is solely based on its ability to bind Grb family proteins, it is proper to further examine the factual evidence regarding the differential expression of Grb7 and Grb14 proteins at the time of filing.

The prior art of record as presented in the articles cited by Appellant fails to support Appellant's statement that "Grb7 and Grb14 are recognized as markers for cancer at the time of filing of the present application" (top at p.8 of the Brief). Specifically, article by Daly (Cell

Signal, 1998, 10, 613-618) presents data regarding tissue distribution of Grb7 and Grb14, which are disclosed as being highly expressed in wide variety of different normal tissues (p.614, second column). Further, publication by Stein et al. (EMBO, 1994, 13, 6, 1331-40) discloses correlation between overexpression of Grb7 and ErbB2 in breast cancer cell lines as well as primary breast cancer specimens (p.615, first column); however, the article makes it clear that research data of Grb7 being associated with breast cancer was inconclusive at the time of publication: "[w]hether GRB-7 expression, like HER-2, has prognostic significance in patients with primary breast cancer remains to be seen. Although our data indicate a highly significant correlation between overexpression of HER-2 and overexpression of GRB-7 in patient samples, the relationship is imperfect; 24 out of the 34 specimens overexpression HER-2 also overexpressed GRB-7 but 10 do not".

Further, it is well settled in the art of cell biology that cancer cell lines differ in a number of respects from the cancer cells from which they have derived. Fundamental aspects of these differences include differential expression of proteins, cell-cycle time and responsiveness to cytotoxic drugs. As discussed in the article by Baguley et al. (Baguley et al., 2004, European J. Cancer, Vol. 40, pp. 794-801), "a potential weakness of [human tumour] cell lines is that they may have lost important properties originally possessed *in vivo*, including potential targets for therapy" (see abstract). One skilled in the art appreciates that cancer cell lines derive from primary cancer cells through a process of immortalization, which results in a significant alteration in the level and type of proteins expressed by that cell. Whereas it is well known that the transformation of a "normal" cell into a cancer cell can result from an alteration of a single gene, the process of immortalization appears to be much more complex and has a more profound

effect on the protein expression profile. Also, the differences between "normal", cancer cells and cancer cell lines are often assumed to reflect features of normal versus malignant biology, but instead are due to different culture conditions. A "normal" cell *in vivo* grows in an environment that is substantially different from the *in vitro* environment of the cell line (artificial culture media, monolayer cultures versus three-dimensional *in vivo* conditions etc.). One of ordinary skill would reasonably expect that changes in the environment in which a cell grown would result in a substantial alteration in the level and type of proteins expressed by that cell. Furthermore, according to the information available in the art, the rate of cell proliferation of primary cancer cells is different from the corresponding cancer cell line (Baguley et al., p.795, section 2). Finally, cancer cell lines appear to be less sensitive to cytotoxic drugs, including critical anticancer inhibitors of EGFR tyrosine kinase, as compared to primary cancer cultures (page 798, section 4). Therefore, one skilled in the art of cell biology would reasonably conclude that the observed overexpression of Grb14 protein in a prostate or breast cancer cell line cannot be unequivocally indicative of Grb14 being a marker for these types of cancer (see publication of Daly et al, 1996, J. Biol. Chem., 271, 12502-10).

Further, articles of Kishi et al. and Tanaka et al. relate to coexpression and co-amplification of Grb7 in gastric and esophageal cancers, respectively. The instant specification, as filed, lacks any reference to an assertion of a specific utility of 2.2412 encoding polynucleotides in these types of cancer. Applicant is reminded that the patent law requires that the specific and substantial credible utility of the claimed invention must be fully disclosed at the time of filing.

At page 9 of the Brief, Appellant submits that "the standard used by the Examiner for satisfying the utility requirement is higher than that set forth in the § 101 Guidelines or Training Materials" and states that Examiner" has dismissed the relevance of the cited extrinsic evidence". However, as evidenced above, the Examiner did not dismiss any evidence presented during the prosecution of the instant application and fully considered all the publications presented by Appellant. Based on the examination of the evidence, the Examiner maintains the position that at the time of filing the specific and substantial credible utility of the instant claimed molecules as cancer markers was not established. The assertion that a novel 2.2412 protein encoded by the claimed polynucleotide is a useful marker for prostate and breast cancer is not supported by any evidence of record presented in the instant specification or substantiated by reference to the prior art of record.

According to legal standard, a specification can meet the utility and enablement requirement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide (an "evidence"), or a well-established utility for the claimed polynucleotide would be *prima facie* obvious to the skilled artisan ("sound scientific reasoning"). Thus, the law requires that the patent application describes the utility of the claimed invention based on evidence or obviousness to one skilled in the art. In the instant case, because the assertion of the utility of polynucleotides encoding 2.2412 protein as a tumor marker is not supported by any evidence of record, such as data showing differential expression of 2.2412 protein in healthy *versus* cancerous tissue, or a mutated form of a polynucleotide specifically associated with certain types of cancer, mere statement that "detection of the encoded protein should provide a useful tumour marker and/or prognostic

indicator" (page 1, lines 4-5 of the instant specification) does not support such assertion. Therefore, one skilled in the art using the instant disclosure, as originally filed, would clearly not be able to diagnose any cancer due to the lack of critical information regarding specific association of 2.2412 and a particular type of cancer.

At page 10 of the Brief, Appellant argues that "[t]he burden is on the Office to substantiate any reasons for doubting an asserted utility". Appellant further refers to the Declaration of Hitoshi to support the utility of the claimed polynucleotides as cancer markers.

The Declaration of Hitoshi under 37 CFR 1.132 filed on February 10, 2003 is insufficient to overcome the rejection of the instant claims as set forth in the last Office action because: the Declaration presents additional information regarding expression of 2.2412 protein using Taqman assay. Specifically, additional data show that 2.2412 was expressed at significantly higher levels in two types of lung cancer and in three types of breast cancer. First, there is no disclosure of any specifics about "higher" levels, or critical levels of distribution, which are specifically associated with cancer pathology, or, alternatively, normal range of distribution. If a clinician took a breast tissue sample from a patient with suspected lung cancer, what is the likelihood that when compared with normal tissue, the level of a polypeptide of SEQ ID NO: 2 from the patient would be higher? How many samples would be needed? What sensitivity would be needed? Would the normal tissue have to be a pooled sample or could it be from a single individual? The Declaration provides only limited information regarding the smallest representative number of samples, which appear to be taken form samples of different types of breast cancers. Therefore, the limited data presented in the Declaration regarding higher levels of

2.2412 in two types of lung cancer and in three types of breast cancer cannot support the asserted utility of the claimed molecules as markers for prostate and breast cancer.

Moreover, the instant specification, as filed, clearly states that the novel 2.2412 is broadly expressed in all normal tissues under normal conditions. 35 U.S.C. § 101 makes it clear that any further subsequent characterization of the claimed DNA and encoded protein, which leads to the discovery of a specific and substantial credible utility is considered to part of the act of invention. Unless credible specific and substantial utility of the claimed compound is disclosed in the specification as filed, Appellant's claimed invention is incomplete. "[A] patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion". *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966).

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher,* 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility" 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Id.*

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because "[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection

of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage," (*Id.*, slip op. at 15), in the instant case detection of an isolated polynucleotide molecule of SEQ ID NO: 1 or the encoded polypeptide of SEQ ID NO: 2 provides no information regarding presence or absence of any pathological condition, including breast, prostate or other form of cancer.

At page 10, Appellant argues that *Fisher* case is one dealing with ESTs and "[u]nlike in *Fisher* case, Appellant's utility statement is supported by evidence". However, *Fisher* case obviously is not limited to ESTs. The case provides analysis of determination of utilities based merely on a hypothetical possibility to achieve an objective, while 35 U.S.C. § 101 requires that the claimed invention is fully supported by clearly identified specific and substantial credible utility at the time of filing. In the instant case, using *Fisher* Appellant's asserted utility is a use which so vague as to be meaningless. The instant specification presents disclosure of the limited data regarding a novel protein ubiquitously expressed in almost all tissues, which is found to be capable of non-specific binding to the other protein within an artificial experimental set environment. Because the other protein belongs to a family of proteins, some of which show non-consistent differential expression in samples of certain primary cancers and cancer cell lines, it is hypothesized that the polynucleotides encoding instant novel protein are useful as markers for prostate and breast tumors. However, the evidence of record is inadequate to support this hypothesis. *Fisher* court held that, "in addition to providing a 'substantial' utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

With respect to Appellant's request for clarification regarding the basis of the instant utility rejection (page 11 of the Brief), Appellant's attention is directed to MPEP 2107. II, section B, which states:

"(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible" (emphasis added). Thus, for purpose of clarification, Appellant's asserted utility must be specific and substantial credible to meet the requirements of 35 USC §101. Further, MPEP 2107. II, section B also states that

"(ii) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant 's assertions".

Thus, contrary to Appellant's statement, MPEP specifically recites a requirement to present disclosure or evidence of record to support an asserted utility. Because in the instant case the instant specification fails to present any evidence or sound scientific reasoning that the instant claimed polynucleotides could be used as cancer biomarkers, the instant claimed invention clearly lacks utility in currently available form and therefore, does not meet the requirement of 35 USC §101.

Applicant's asserted utility for the polynucleotide encoding the polypeptide 2.2412 of SEQ ID NO: 2, particularly in view of a lack of knowledge as to the biological function or physiological relevance to cancer of the polypeptide of SEQ ID NO: 2, the type of cancer which can be diagnosed and how much of 2.2412 polypeptide/polynucleotide is indicative of disease, constitutes a utility that requires further research to identify or reasonably confirm a "real world"

context of use. See *Brenner v. Manson*, 148 USPQ at 696. While an assay that detects the presence of an agent that has a stated correlation to a predisposition or presence of a specific disease condition would be considered a "substantial utility" in the context of identifying potential candidates for preventive measures, in the instant case the claimed polynucleotides are suitable only for future research.

Thus, for reasons set forth and also reasons of record in the previous communications of record, the claimed polynucleotides do not have a real-world use and do not meet the utility requirements under 35 U.S.C. 101.

Further, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

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